WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising a saturated cladribine-cyclodextrin complex formulated into a solid oral dosage form or a transmucosal dosage form, said composition being substantially free of cyclodextrin in excess of the minimum amount required to maximize the amount of cladribine in the complex.

2. A pharmaceutical composition comprising a saturated cladribine-cyclodextrin complex formulated into a solid oral dosage form or a transmucosal dosage form, said composition being substantially free of cyclodextrin in excess of the minimum amount required to maintain substantially all of the cladribine in the complex.

3. The composition according to Claim 1 or 2, wherein the saturated cladribine-cyclodextrin complex is formulated into a solid oral dosage form.

4. The composition according to Claim 1, 2 or 3, wherein the cyclodextrin is γ-cyclodextrin, hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, dimethyl-β-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

5. The composition according to Claim 1, 2 or 3, wherein the cyclodextrin is γ-cyclodextrin.

6. The composition according to Claim 1, 2 or 3, wherein the cyclodextrin is hydroxypropyl-β-cyclodextrin.

7. The composition according to Claim 5, wherein the complex comprises a 1:2 cladribine:γ-cyclodextrin complex.

8. The composition according to Claim 4, 5 or 6, wherein the weight ratio of cladribine to cyclodextrin is from about 1:35 to about 1:50.

9. The composition according to Claim 5, wherein the weight ratio of cladribine to γ-cyclodextrin is about 1:46.

10. The composition according to Claim 6, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:42.

11. The composition according to any one of Claims 2 to 6, wherein the approximate molar ratio of cladribine to cyclodextrin corresponds to a point located on a phase solubility diagram for saturated complexes of cladribine in varying concentrations of the cyclodextrin.

12. The composition according to Claim 11, wherein the cyclodextrin is γ-cyclodextrin and the point is taken from the portion of the phase solubility diagram indicative of formation of a 1:2 complex of cladribine:γ-cyclodextrin.

13. A method for enhancing the oral or transmucosal bioavailability of cladribine comprising administering to a subject in need thereof a pharmaceutical composition comprising a saturated cladribine-cyclodextrin complex formulated into a solid oral dosage form or a transmucosal dosage form, said composition being substantially free of cyclodextrin in excess of the minimum amount required to maximize the amount of cladribine in the complex.

14. A method for enhancing the oral or transmucosal bioavailability of cladribine comprising administering to a subject in need thereof a pharmaceutical composition comprising a saturated cladribine-cyclodextrin complex formulated into a solid oral dosage form or a transmucosal dosage form, said composition being substantially free of cyclodextrin in excess of the minimum amount required to maintain substantially all of the cladribine in the complex.

15. The method according to Claim 13 or 14, wherein the saturated cladribine-cyclodextrin complex is formulated into a solid oral dosage form.

16. The method according to Claim 13, 14 or 15, wherein the cyclodextrin is γ-cyclodextrin, hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, dimethyl-β-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

17. The method according to Claim 13, 14 or 15, wherein the cyclodextrin is γ-cyclodextrin.

18. The method according to Claim 13, 14 or 15, wherein the cyclodextrin is hydroxypropyl-β-cyclodextrin.

19. The method according to Claim 17, wherein the complex comprises a 1:2 cladribine:γ-cyclodextrin complex.

20. The method according to Claim 16, 17 or 18, wherein the weight ratio of cladribine to cyclodextrin is from about 1:35 to about 1:50.

21. The method according to Claim 17, wherein the weight ratio of cladribine to γ-cyclodextrin is about 1:46.

22. The method according to Claim 18, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:42.

23. The method according to any one of Claims 14 to 18, wherein the approximate molar ratio of cladribine to cyclodextrin corresponds to a point located on a phase solubility diagram for saturated complexes of cladribine in varying concentrations of the cyclodextrin.

24. The method according to Claim 23, wherein the cyclodextrin is γ-cyclodextrin and the point is taken from the portion of the phase solubility diagram indicative of formation of a 1:2 complex of cladribine:γ-cyclodextrin.

25. A method for the treatment of symptoms of a cladribine-responsive condition in a subject suffering from said symptoms comprising administering to said subject a pharmaceutical composition comprising a saturated cladribine-cyclodextrin complex formulated into a solid oral dosage form, said composition being substantially free of cyclodextrin in excess of the minimum amount required to maximize the amount of cladribine in the complex.

26. A method for the treatment of symptoms of a cladribine-responsive condition in a subject suffering from said symptoms comprising administering to said subject a pharmaceutical composition comprising a saturated cladribine-cyclodextrin complex formulated into a solid oral dosage form, said composition being substantially free of cyclodextrin in excess of the minimum amount required to maintain substantially all of the cladribine in the complex.

27. The method according to Claim 25 or 26, wherein the cladribine-responsive condition is selected from the group consisting of multiple sclerosis, rheumatoid arthritis and leukemia.

28. The method according to Claim 27, wherein the cladribine-responsive condition is multiple sclerosis.

29. The method according to Claim 25, 26, 27 or 28, wherein the saturated cladribine-cyclodextrin complex is formulated into a solid oral dosage form.

30. The method according to any one of Claims 25 to 29, wherein the cyclodextrin is γ-cyclodextrin, hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, dimethyl-β-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

31. The method according to any one of Claims 25 to 29, wherein the cyclodextrin is γ-cyclodextrin.

32. The method according to any one of Claim 25 to 29, wherein the cyclodextrin is hydroxypropyl-β-cyclodextrin.

33. The method according to Claim 30, 31 or 32, wherein the weight ratio of cladribine to cyclodextrin is from about 1:35 to about 1:50.

34. The method according to Claim 31, wherein the weight ratio of cladribine to γ-cyclodextrin is about 1:46.

35. The method according to Claim 32, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:42.

36. The method according to Claim 31, wherein the complex comprises a 1:2 cladribine:γ-cyclodextrin complex.

37. A method for enhancing the bioavailability of cladribine from a solid oral or transmucosal dosage form administered to a mammal in need of treatment with cladribine, said method comprising:

(a) determining the minimum amount of cyclodextrin required to complex with a selected amount of cladribine and to maintain said selected amount of cladribine in the complex;

(b) combining an amount of cladribine in excess of said selected amount with said minimum amount of cyclodextrin in an aqueous medium;

(c) removing uncomplexed cladribine from the aqueous complexation medium;

(d) removing water from the aqueous complexation medium to afford the dry saturated cladribine-cyclodextrin complex;

(e) formulating said dry saturated cladribine-cyclodextrin complex into a solid oral dosage form or a transmucosal dosage form substantially free of cyclodextrin in excess of the minimum amount required to maintain substantially all of the cladribine in the complex; and

(f) administering said dosage form orally or transmucosally to said mammal.

38. Use of a saturated cladribine-cyclodextrin complex in the formulation of a solid oral dosage form or a transmucosal dosage form substantially free of cyclodextrin in excess of the minimum amount required to maximize the amount of cladribine in the complex, for administration in the treatment of symptoms of a cladribine-responsive condition.

39. Use of a saturated cladribine-cyclodextrin complex in the formulation of a solid oral dosage form or a transmucosal dosage form substantially free of cyclodextrin in excess of the minimum amount required to maintain substantially all of the cladribine in the complex, for administration in the treatment of symptoms of a cladribine-responsive condition.

40. Use according to Claim 38 or 39, wherein the cladribine-responsive condition is selected from the group consisting of multiple sclerosis, rheumatoid arthritis and leukemia.

41. Use according to Claim 40, wherein the cladribine-responsive condition is multiple sclerosis.

42. Use according to Claim 38, 39, 40 or 41, wherein the saturated cladribine-cyclodextrin complex is formulated into a solid oral dosage form.

43. Use according to any one of Claims 38 to 42, wherein the cyclodextrin is γ-cyclodextrin, hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, dimethyl-β-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

44. Use according to any one of Claims 38 to 42, wherein the cyclodextrin is γ-cyclodextrin.

45. Use according to any one of Claims 38 to 42, wherein the cyclodextrin is hydroxypropyl-β-cyclodextrin.

46. Use according to Claim 43, 44 or 45, wherein the weight ratio of cladribine to cyclodextrin is from about 1:35 to about 1:50.

47. Use according to Claim 44, wherein the weight ratio of cladribine to γ-cyclodextrin is about 1:46.

48. Use according to Claim 45, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:42.

49. Use according to Claim 44, wherein the complex comprises a 1:2 cladribine:γ-cyclodextrin complex.

50. Use of a saturated cladribine-cyclodextrin complex in the formulation of a solid oral dosage form or a transmucosal dosage form substantially free of cyclodextrin in excess of the minimum amount required to maximize the amount of cladribine in the complex, for enhancing the oral or transmucosal bioavailability of cladribine.

51. Use of a saturated cladribine-cyclodextrin complex in the formulation of a solid oral dosage form or a transmucosal dosage form substantially free of cyclodextrin in excess of the minimum amount required to maintain substantially all of the cladribine in the complex, for enhancing the oral or transmucosal bioavailability of cladribine.

52. Use according to Claim 50 or 51, wherein the saturated cladribine-cyclodextrin complex is formulated into a solid oral dosage form.

53. Use according to Claim 50, 51 or 52, wherein the cyclodextrin is γ-cyclodextrin, hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, dimethyl-β-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

54. Use according to Claim 50, 51 or 52, wherein the cyclodextrin is γ-cyclodextrin.

55. Use according to Claim 50, 51 or 52, wherein the cyclodextrin is hydroxypropyl-β-cyclodextrin.

56. Use according to Claim 53, 54 or 55, wherein the weight ratio of cladribine to cyclodextrin is from about 1:35 to about 1:50.

57. Use according to Claim 54, wherein the weight ratio of cladribine to γ-cyclodextrin is about 1:46.

58. Use according to Claim 55, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:42.

59. Use according to Claim 54, wherein the complex comprises a 1:2 cladribine:γ-cyclodextrin complex.

60. A 1:2 cladribine:γ-cyclodextrin complex.

61. A mixture of a 1:1 cladribine:γ-cyclodextrin complex and a 1:2 cladribine:γ-cyclodextrin complex, wherein the 1:2 complex is predominant.